b) Patient information leaflet

The under-mentioned information with regard to this medicine shall appear on the patient information leaflet. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to Regulation 10 of the Act).

1 Scheduling status

2 Proprietary name and dosage form

3 Composition of the medicine, that is, what this medicine contains

4 Approved indication and use, that is, what this medicine is used for

5 Instruction before taking the medicine

6 Instructions on how to take the medicine

7 Side effects

8 Storage and disposal information

9 Presentation

10 Identification

11 Registration number

12 Name and business address of the holder of the certificate of registration

13 Date of publication of the Patient Information Leaflet.

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you

This medicine is available without a doctor's prescription, for you to treat a fungal infection.

Nevertheless you still need to use Canesten® Topical Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days or if symptoms have not disappeared in 7 days.

SCHEDULING STATUS : S1

PROPRIETARY NAME (AND DOSAGE FORM):

Canesten® Topical Cream

WHAT CANESTEN® TOPICAL CREAM CONTAINS :

Topical Cream:

Active ingredient is: Clotrimazole 10 mg/g

The other ingredients are: Benzyl alcohol 2 %, Cetostearyl alcohol, Cetyl palmitate, Octyldodecanol, Polysorbate 60, Purified water, Sorbitan stearate.

WHAT CANESTEN® TOPICAL CREAM IS USED FOR :

Pharmacotherapeutic group

Antifungals

Therapeutic indication

For all fungal infections of the skin caused by moulds, yeasts and fungi and also for skin diseases with secondary infections of these fungi.

These fungal infections may include among others:

1. Fungal infections of the skin and skin folds, (e.g. fungal infections of the groin, perineum, arm pits, Dhobie itch or jock itch and barber's itch.)

2. Ringworm.

3. Fungal infections in-between toes or fingers e.g. athlete's foot.

4. Candida vulvitis (vulval thrush).

5. Candida balanitis, (thrush of the glans penis).

6. Pityriasis (Tinea) versicolor.

7. Erythrasma.

8. Paronychias, associated with nail mycoses, (fungal infections of the tissues adjacent to the nail of a finger or toe).

BEFORE YOU TAKE CANESTEN® TOPICAL CREAM

- Do not use if you are allergic to clotrimazole and/ or cetostearyl alcohol.
- If your skin problem does not improve within 1 week, check with your doctor or pharmacist.
- Direct contact with Canesten® Topical Cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment

Special Warnings:

Not intended for ophthalmic use.

Keep this medicine away from the eyes.

Do not place an occlusive dressing (airtight covering such as kitchen plastic wrap) over the medicine.

Pregnancy and Breast feeding

If you are pregnant or breast feeding your baby while using this medicine please consult your doctor, pharmacist or other health care professional for advice.

Interaction with other medicinal products

Not Known.

HOW TO TAKE CANESTEN® TOPICAL CREAM

Canesten® Topical cream should be applied thinly to the affected areas 2-3 times a day and rubbed in. A small amount of cream is usually sufficient for an area about the size of a palm. Successful treatment demands that CANESTEN be applied correctly and over a sufficiently long period of time. The normal period of treatment is 3-4 weeks.

Topical treatment of fungal infections should be continued for approximately 2 weeks after the disappearance of all symptoms despite a rapid, subjective improvement, in order to prevent relapse.

For the treatment of athlete's foot and other fungal infections in skin folds it is important to dry the area carefully.

POSSIBLE SIDE EFFECTS

- Local reactions including skin irritation and burning may occur.
- Contact allergic dermatitis has been reported.
- In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.
- Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF CANESTEN® TOPICAL CREAM

Keep all medicines out of the reach of children.

Store below 25°C.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

PRESENTATION OF CANESTEN® TOPICAL CREAM

A 20 g collapsible aluminium tube contained in a cardboard carton.

IDENTIFICATION OF CANESTEN® TOPICAL CREAM

A soft, white cream

REGISTRATION NUMBER : E/20.2.2/49

NAME AND ADDRESS OF THE REGISTRATION HOLDER :

Bayer (Pty) Ltd
27 Wrench Road Isando 1600
Reg No 1968/011192/07

DATE OF PUBLICATION OF THIS PACKAGE INSERT : ~~April 1995~~ Pending

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